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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MEMORANDUM

JUL 1 3 1983

TO:

Richard Mountfort, PM#23

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Registration Division (TS-767)

THRU:

David Ritter, Acting Section Head DLR 7-7-27

Toxicology Branch/HED (TS-769)

SUBJECT:

Thidiazuron (DROPP) 2139-122: Review and Evaluation of the revised Protocol for the Chromosome Aberrations in Human Lymphocytes with and without in-vitro Metabolic Activation (Litton Bionetics Protocol No. 449.1 -

CASWELL#659A Edition 6).

Comments on Litton Bionetics responses to the deficiencies noted in the previous TB review of 4/21/83 for the protocol of human lymphocytes cytogenetics:

- The preliminary test procedure for mitotic suppression and cell cycle delay submitted for the dose determination in this test system is acceptable. The include details with respect to the maximum dose determination are reasonable. Registrant has provided the information asked for.
- Registrant's statement for the selection of one-hour exposure time under the in-vitro metabolic activation (S9 mix) is justified and acceptable.
- The modification of procedures with respect to the hypotonic treatment, cell fixation, and chromosome slide preparation is adequate. Registrant's response relives the deficiencies with respect to the lymphocyte fixation.

## Recommendation:

Toxicology Branch considers the revised protocol for the invitro human lymphocytes cytogenetics is acceptable.

John H.S. Chen, D.V.M.

Review Section #1

Toxicology Branch/HED (TS-769)